STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES

Office of Pharmacy Service
Prior Authorization Criteria

PCSK-9 INHIBITORS
PRALUENT®(alirocumab), REPATHA® (evolocumab)
Effective 03/05/2018

Prior Authorization Request Form

- ***REPATHA®*** *is a PCSK9 (Proprotein Convertase Subtilisin Kexin Type 9) inhibitor antibody indicated:*
  - *to reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease.*
  - *as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of LDL-cholesterol (LDL-C).*
  - *Repatha is also indicated as an adjunct to diet and other LDL-lowering therapies in patients with homozygous familial hypercholesterolemia (HoFH) who require additional lowering of LDL-C.*

- ***PRALUENT®*** *is a PCSK9 (Proprotein Convertase Subtilisin Kexin Type 9) inhibitor antibody indicated as adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of LDL-cholesterol (LDL-C).*

****** FOR ALL indications, WV MEDICAID requires the PCSK-9 Inhibitors to be used in combination with an optimized regimen of lipid-lowering therapy (e.g., high-intensity statin) unless there is a clinically demonstrated intolerance to statin therapy (see below for details on monotherapy).***

CRITERIA FOR APPROVAL

1) Must be prescribed by or in consultation with a cardiologist, lipid specialist, or endocrinologist; **AND**

2) Prior authorization request must be for an FDA-approved indication (as listed above) and clinical documentation supporting the diagnosis must be submitted with the request; **AND**

3) Documentation must be submitted indicating that the patient has failed to reach an LDL<70 mg/dL after 8-week trials of **both** atorvastatin 40 to 80 mg and rosuvastatin 20 to 40 mg (prescribed at the maximally tolerated dose) **AND** at least one of these trials must include a concurrent trial of ezetimibe. **In both trials, documentation must clearly indicate an attempt was made to maximize the statin dose** and patient adherence to all statin/ezetimibe trials must be evidenced by consistent pharmacy claims.

4) Should the patient be unable to tolerate the recommended dosing for high-intensity statin therapy, the patient will be required to trial at least **two (2)** other lipid-lowering agents with a statin prescribed at the maximally tolerated dose, unless doing so would be unlikely to achieve the goal LDL.

CRITERIA FOR CONTINUATION

1) Documentation of efficacy indicated by at least a 40% LDL-C reduction from pre-treatment level; **AND**

2) Documentation that the member has been adherent to concurrent treatment with statin and PCSK9 inhibitor as demonstrated by consistent pharmacy claims. Note: Ezetimibe and other lipid lowering agents may be discontinued at the discretion of the clinician once the patient has been established on the PCSK9 inhibitor.

PCSK-9 INHIBITOR MONOTHERAPY DUE TO STATIN INTOLERANCE

PCSK-9 inhibitor monotherapy is approvable **only** on appeal to the BMS Medical Director.

Approval of monotherapy with any PCSK9 inhibitor requires documentation that the patient has previously experienced rhabdomyolysis while on a statin OR that the prescriber has personally tested the patient for a physiological statin intolerance. Verification of intolerance requires laboratory findings indicating significant elevation in creatine kinase levels (typically > 10x the upper normal limit). **Simple documentation that the patient had muscle cramps/spasms or "myopathy" is NOT sufficient for approval as monotherapy.**

The following is an example of an acceptable strategy for proving statin intolerance:

A minimum of three statins must be trialed, two of which must be high-intensity statins (atorvastatin to a goal of 40-80 mg or rosuvastatin to a goal of 20-40 mg).

High intensity statin #1→ Patient experiencing adverse effects→ If appropriate, discontinue statin and allow a 2-week washout period→ Attempt to re-initiate the same statin at a lower dose and titrate upward as tolerated. Verification of physical intolerance or toxicity require laboratory findings indicating significant elevation in creatine kinase levels (typically > 10x the upper normal limit).

If failure to tolerate high-intensity statin #1, then switch to high-intensity statin #2 and proceed in a similar fashion. Should the patient fail the second high-intensity statin, the 3rd trial should involve titration of a different statin to the highest dose tolerated. Should the 3rd trial fail, then the patient may be approved for PCSK9 therapy off-label therapy. NOTE: Approval of any PCSK9 therapy is contingent on the patient not being able to reach their goal LDL with the addition of either ezetimibe or a bile acid sequestrant to any current statin therapy tolerated.

REFERENCES

1) Repatha package insert revised 12/2017
2) Praulent package insert revised 7/2015
3) Lexi-Comp Clinical Application reviewed 02/19/2018
4) AACE 2017 Guidelines: American Association of Clinical Endocrinologists and American College of Endocrinology Guidelines for Management of Dyslipidemia and Prevention of Cardiovascular Disease. Endocrine Practice Vol 23 (Suppl 2) April 2017.
5) *UpToDate* clinical article: Management of low density lipoprotein cholesterol (LDL-C) in secondary prevention of cardiovascular disease (last update 7-25-2017)
6) Sabatine et al. Evolocumab and Clinical Outcomes in Patients with Cardiovascular Disease; N Engl J Med 2017; 376:1713-1722
7) Stone, N. J., Robinson, J., Lichtenstein, A. H., et al. 2013 ACC/AHA Guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults: A report of the American College of Cardiology/American Heart Association Task Force on practice guidelines. *Circulation* 2013. Retrieved from: http://circ.ahajournals.org.
8) Goldberg, A. C., Hopkins, P. N., Toth, P. P., et al. Familial hypercholesterolemia: Screening, diagnosis and management of pediatric and adult patients. Clinical guidance from the National Lipid Association Expert Panel on Familial Hypercholesterolemia. *J. of Clinical Lipidology* 2011 Volume 5, Number 3S.
9) Treating Statin Intolerant Patients. Marcello Arca and Giovanni Pigna. Diabetes Metab Syndr Obes. 2011; 4: 155–166.